REMARKS/ARGUMENTS

Amendment to the Claims

Claims 1-5, 7-40, 45, 47-54 are currently in the application. Claims 12, 18, 23-27, 31-35, 37-40, 45, and 47-48 are withdrawn from consideration. Claim 19 is amended. Claim 20 is canceled.

Claim 19 is presently amended to incorporate therein the volumetric flow rate limits of claim 20.

No new matter is added by amendment.

Rejections under 35 USC §103(a)

Claims 1-5, 7-11, 13-17, 19-22, 28-30, 36, and 49-54 are rejected as obvious over Jacobsen (US 6,045,534) and further in view of Flaherty (US 7,303,549), and further in view of Ueda et al. (US 7,252,653 and Rise (US 5,752,930).

Applicant traverses and requests reconsideration and withdrawal of all rejections, and allowance of all claims.

A. The rejection does not meet the legal requirements for rejecting claims under 37 CFR 1.104.

In the last response, the Application requested that the rejection be issued to more particularly specify the prior art references applied to each claim or groups of claims. The Examiner (page 3 and 4, items 4, 5, and 6 of the Final rejection) does not recognize any failure of the rejection under 37 CFR 1.104. The Examiner instead stated that the summary of each reference and what portion thereof was being relied upon, is sufficient to rejection each claim (or group of claims) clearly and specifically.

The Examiner also noted that "applicant fails to disclose the patentable subject matter of each independent claim and what the specific limitation is that overcomes the current rejection". This applicant is not required to provide evidence supporting or proof of patentability (specifically, nonobviousness) when the rejection has failed to produce a *prima facie* obviousness rejection (MPEP 2142), or fails to make a proper rejection under 37 CFR 1.104.

Applicant understands that the Jacobsen reference is the primary reference that applied against all the independent claims (Claims 1, 5, 9, 14, 19, and 28) and claims depending therefrom, except for the elements that were listed, which are understood to be the "specific size of the needle", the "flow rate", and "applying adhesive on the device's housing".

Applicant notes a problem with the rejection right there: Each of the independent claims provide that the housing has "a base for attachment to the skin of the patient". That is, the base attaches to the skin of the patient. Not only does Jacobsen not disclose "applying adhesive", but Jacobsen also does not disclose a base for attachment to the skin of the patient.

The rejection continues, stating that Flaherty discloses a delivery device with retraction means, injection means, and adhesive means that is an adhesive layer on the outer surface of the housing." Applicants note that only claims 49-54 (which dependent to the independent claims) identify a means for attaching the base for semi-permanent attachment to the skin.

The rejection continues, stating that Ueda et la discloses the benefit of having needles with the specifically claimed dimensions.

The rejection continues, stating that Rise et la discloses varying the flow rate from 1 micro liter per minute to 500 micro liter per minute.

Consequently, it is not clear that Claim 1 is being rejected by the applicant based on Jacobsen in view of Ueta et al, **OR** Jacobsen in view of Ueta et al and Flaherty. It seems that Claim 2 requiring a retracting means would require Flaherty, so was Flaherty cited against Claim 1 as well or not?

Consequently, it is not clear that Claim 5 is being rejected based on Jacobsen in view of Flaherty, **OR** Jacobsen in view of Flaherty and Ueta et al., since Claim 5 has a limitation in needle size (less than about 0.38 mm).

Consequently, it is not clear that Claim 9 and Claim 19 are being rejected based on Jacobsen in view of Rise et al only, **OR** Jacobsen in view of Rise et al. and Flaherty, **OR** Jacobsen in view of Rise et al. and Ueta et al, **OR** Jacobsen in view of Rise et al. and Flaherty and Ueta et al. Claim 5 has a limitation in needle size (less than about 0.38 mm), and neither Jacobsen nor Ueta et al disclose a base for attachment to the skin of the patient.

Consequently, it is not clear that Claim 14 is being rejected based on Jacobsen in view of Rise et al and Ueta et al, **OR** Jacobsen in view of Rise et al., Ueta et al and Flaherty, since neither Jacobsen nor Ueta et al disclose a base for attachment to the skin of the patient.

Consequently, it is not clear that Claim 28 is being rejected based on Jacobsen alone, **OR** Jacobsen in view of Flaherty, **OR** Jacobsen in view of Ueta et al, **OR** Jacobsen in view of Flaherty and Ueta et al, since neither Jacobsen nor Ueta et al disclose a base for attachment to the skin of the patient, and since Claim 5 has a limitation in needle size (less than about 0.38 mm). And none of the references appears to describe, and the action does not address, a means for automatically sequencing and activating the inserting means, pumping means and retracting means.

Therefore, the rejection is not clear and should be withdrawn and restated with specificity of the particular references to each claim.

B. The rejection fails to state a prima facie obviousness rejection

Notwithstanding the failure of the action under Rule 37 CFR 1.104, the rejection also fails to state a prima facie obviousness rejection.

Jacobsen (US 6,045,534) discloses: an autoinjection device that utilizes a piston-like assembly and a propellant to automatically inject a single dose of a drug into a person when the propellant is activated [Field of the Invention]; an autoinjection device that quickly administers the drug [Summary of the Invention, column 2 lines 39-40]; a pressure source preferably comprises a highly combustible material, such as a propellant, that forms a gas when ignited, and an igniter to ignite the combustible material [Summary of the Invention, column 3 lines 17-19]; the ignition of the propellant (the combustible material) occurs in short period of time, 500 milliseconds [column 5 lines 3-8]; that after ignition, circuitry is activated and heats another resistor 55 for a period of time (e.g., 0.5 seconds) to melt a solder, which allows the gases generated by ignition of the propellant to escape and allow a coil spring to retract the needle [column 5 lines 18-26]. A person of ordinary skill would understand that Jacobsen is a hand-held injection device that delivers the vaccine in a matter of a second or a couple of seconds.

Flaherty is attributed to teaching the use of an adhesive layer on the housing of an injection device that allows the flexing of the skin during attachment and aids the patient's comfort. Flaherty discloses a drug infusion device, which contemplates infusing the drug from a reservoir through a cannula of the period of three days [column 37 line 60 through column 38 line 2].

With regarded to any alleged combination of Jacobsen and Flaherty (and it is not clear

that the Examiner has rejected any single claim based solely on Jacobsen and Flaherty), *Applicant traverses*.

Jacobsen teaches an autoinjector that injects a dose of vaccine and retracts the needle in something like 1 second. Flaherty teaches a drug infusion device that meters the drug through an inserted cannula over a several-day period. It is not predictable, and frankly inconceivable, that a person of ordinary skill would consider a combination of these two references teaching different devices that deliver a fluid through a needle over such immensely different period frame. Furthermore, it is unpredictable that one of ordinary skill would consider applying an adhesive layer of Flaherty on the autoinjector of Jacobsen; Jacobsen discloses or suggests applying the device to the skin of the patient for not more than about a second. It would seem that a person of ordinary skill might consider that applying an adhesive (of Flaherty) onto the portion of the autoinjector (of Jacobsen) that comes into contact with the skin might be counter-effective, since it could tend to adhere the autoinjector unintentionally and slow the injection process. There simply no reason for a person of ordinary skill to even consider attaching an adhesive layer to the autoinjection device of Jacobsen. Put simply, a person of ordinary sill would not have recognized that the result of this combination was predictable. And, there is no teaching, suggestion, or motivation, in either of the references or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of these two references.

It is also known that pain is associated with the injection of medicaments as the rapid accumulation of the liquid medicament can tear the muscle tissue or other body tissue. (See Applicant's specification, page 1, last paragraph.) In Jacobsen, the injection of the liquid appears to occur in about a second or so, comparable to conventional hand-held syringe injections, which would reasonable effect such pain. It would thus not be predictable to employ a smaller diameter needle, as taught by the present invention, in the device of Jacobsen because the person of ordinary skill would give no consideration to the avoidance of pain associated with a smaller diameter needle. Besides, the use of a smaller-diameter needle in the device of Jacobsen would inherently increase the back pressure of the injection liquid within the device, and perhaps decrease the effective flow rate, which appears contrary to the teaching in Jacobsen of an autoinjection device that quickly administers the drug within about a second.

The examiner makes the allegation at page 4, items 7 and 8 of the Action, that Jacobsen in an injector "applied to the outer skin and thus would be improved if an adhesive layer was

applied to the injector especially since Flaherty discloses an expectation of advantage when using an adhesive layer", and that Jacobsen teaches a housing with a base for attachment to the skin since "the base of Jacobsen attaches to the skin of the patient". Where does Jacobsen say that the injector is "applied to the skin"? Where does Jacobsen say, suggest or imply that the autoinjector of Jacobsen "attaches" to the skin? With all due respect, what Jacobsen might describe is "touching" of the autoinjector to the skin, and "touching" does not describe "attaching". The examiner's rationale and conclusion are completely without basis in fact, and are at the very best, speculative and contrary to that which a person of ordinary skill might understand from the references.

The rejection also states that **Ueda** and **Rise** show how a person of ordinary skill would find it obvious to try and modify the prior art reference to the needle and the flow rate that meets the needs of the infusion rate that is prescribed by the physician and thus fulfilling the claim requirements of the Applicants' invention.

Applicant traverses.

The **Ueda** et al. reference (US 7,252,653, filed (PCT) Jan 23, 2002), discloses a tapered injection needle affixed to the end of a hand-held syringe for injecting the liquid. The rejection states that Ueda et al. discloses the "benefit of having needles with the specific claimed dimensions". That's untrue. Ueda et al. teaches a non-standard needle that tapers from the small-diameter injection end to an anchoring part 22, which is sized larger that the insertion part 21 of the needle in order to reduce liquid flow resistance (column 7, lines 5-8) and to improve attachment of the needle to the supporting part 3 of the hand-held syringe (column 7, lines 27-30). Ueda notes that the small diameter injection end or tip provides less injection (needle insertion) resistance and pain (column 1, lines 55-67), but creates significant backpressure when injecting liquids by hand, which can make it difficult to inject the complete dose (column 2, lines 5-11) or can result in a larger, heavier device that is harder to handle by hand (column 2, lines 20-33).

First, any alleged combination of references that includes Ueta et al may not simply substitute the "needle size" of Ueta et al. Ueta et al very specifically and intentional discloses a needle that is fine and tapered at one end, and large and attachable to a cannula at the other end. The Examiner may not pick one feature off of an element in an prior art, and apply that feature in

a combination rejection when such isolated element would cease to function as required in its source reference (that is, are required in Ueta et al).

Second, the rejection alleges an "obvious to try" standard for combining the needle size of Ueda with the device of Jacobsen. However, the "obvious to try" standard requires that there be "(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem; (and) (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success." The Ueda teaching clearly fails the "obvious to try" criteria. The needle taught in Ueda requires a needle that tapers from the injection end to an anchoring part, which is purposely sized larger that the insertion part of the needle in order to reduce liquid flow resistance and to improve attachment of the needle to the supporting part of the syringe. None of the alleged "finite number" of needles of Ueda et al could possibly be substituted for the needle in Jacobsen, with any reasonable expectation of success. Therefore, a person of ordinary skill in the art would not have recognized or predicted that applying the technique of Ueda et al. would have yielded predictable results in the device of Jacobsen, which requires that the needle have both ends shaped to pierce – at one end, the skin, and at the other end, the puncture seal of the reservoir, while the non-standard needle of Ueda clearly does not.

Also, both the Jacobsen and the Ueda devices are hand-held devices configured to deliver the liquid medicament as quickly as possible into the body. Neither Jacobsen nor Ueda provide a housing having a base for attachment to the skin of the patient, as provided by Applicant's claims.

The **Rise** reference (US 5,752,910) teaches using a syringe with a hypodermic needle 16 to rapidly fill an under-the-skin infusion (injection) device through a septum 18 in a port 14 disposed in the injection device, as seen in Fig. 1 and described at column 2, line 66 to column 3, line 6. First, it is important to distinguish the flow and operating from the infusion pump from that of the syringe. The infusion pump does not inject liquid through a hypodermic needle. The flow rate identified by the examiner in the action in Rise is 1 μL/min to 5000 μL/min. This flow rate is the intermittent, instantaneous flow rate of medication through the infusion catheter at a high pressure to ensure that the target amount of medication flows to each of the openings in the catheter to the spaced infusion sites. See Rise et al at column 6 lines 30-58. For a second, typically much longer, time period, the pressure of the fluid is reduced to ensure that the liquid

does not flow through any openings in the catheter tip. Rise et al states that this alleged flow rate occurs only in very short bursts covering a first time period ranging from 0.01 seconds to 2.0 seconds, while the flow rate is shut off or zero during a succeeding second time period that runs from 8 seconds to 672 hours. A person of ordinary skill consulting Rise would unquestionably recognize that the flow rate is an intermittent flow rate of short duration, and not a "substantially constant volumetric flow rate", as required in Applicant's independent Claims 9 and 14, and several dependent claims (10, 15 and 29). Rise et al does describe an average flow rate, at in claim 7, namely 0.01 μL/hr (2.8×10^{-6} μL/sec) to 20 μL/min (0.33 μL/sec), which is completely outside the Applicants' claimed substantially constant flow rates.

Finally, the rejection makes a general allegation that "the flow rate and the size of the needle diameter . . . are well known variables that depend on the type of medication, size of the apparatus and form of treatment and are constantly modified depending on medical procedure." Applicant respectfully considers that such statement is a generalized opinion and is without any factual basis, and cannot replace or substitute for the identification of specific prior art references that anticipate or make obvious Applicant's claimed invention. In particular, Applicant points out that the identified substantially constant flow rate in various of Applicant's claims of 0.5-20 μL/sec will deliver a standard 0.5cc vaccine in a time period between 25 seconds and 16 minutes, while the more specific flow rate of 1-4 μL/sec will deliver the 0.5cc vaccine in about 2-8 minutes, which time periods are generally sufficiently slow to allow the injected medication to be diffused into the body to prevent the typical intense pain caused by the nearly instantaneous injection of the entire 0.5 cc into the muscle by devices such that those described in Ueta et al and Jacobsen. See Applicant's description, the last paragraph of page 13. None of the prior art references cited by the examiner disclose this problem or make suggestion of a solution thereto.

Therefore, Applicant believes that the rejection fails to state a *prima facie* obviousness rejection against any of the claims.

Rejoinder of Withdrawn Claims

In view of the arguments clearly distinguishing the examined claims over the prior art of record, Applicant requests rejoinder of the withdrawn claims 12, 18, 23-27, 31-35, 37-40, 45, and 47-48, and consideration of the patentability of the same.

Prosecution of commonly-owned, co-pending patent applications with related subject matter

Applicant points out the following prosecution items to the Examiner in commonly-owned, co-pending patent applications with related subject matter:

1. US Appln. 10/597,991, file June 7, 2007, (Wall et al), under Non-Final rejection mailed January 26, 2009, citing Miskinyar (US 5527287), Woehr et al. (US 20030144627), McWethy et al. (US 7004929), Flaherty (US 6,749,587) and Landau (US 6,264,629).

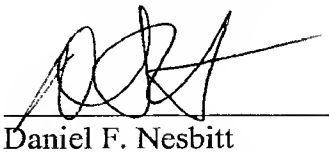
2. US Appln. 10/597,997, file June 7, 2007, (Wall et al), under Non-Final rejection mailed February 12, 2009, citing McConnell-Montalvo et al (US 6939330), Woehr et al. (US 20030144627), and Hunn et al (US 2004/0158207).

Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests rejoinder of the withdrawn claims and a prompt allowance of all claims.

Respectfully submitted,

For: Eric James WALL

By: 

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